

October 17, 2008 with respect to certain avian influenza viruses; minor modifications are necessary to correct previous, minor, editorial errors; and republication of the Original Declaration, as amended, in its entirety is necessary for clarity;

Whereas, the findings made by the Secretary in the Original Declaration, as amended, continue to apply generally, and apply with equal force as to the 2009 H1N1 influenza;

Whereas, in accordance with section 319F–3(b)(6) of the Act (42 U.S.C. 247d–6d(b)), I have considered the desirability of encouraging the design, development, clinical testing or investigation, manufacturing, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, and use of additional covered countermeasures with respect to the category of disease and population described in sections II and IV of the Original Declaration, as amended, and as hereby further amended, and have found it desirable to encourage such activities for these additional covered countermeasures, and;

Whereas, to encourage the design, development, clinical testing or investigation, manufacturing and product formulation, labeling, distribution, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, and use of medical countermeasures with respect to the category of disease and population described in sections II and IV of the Original Declaration, as amended, and as hereby further amended, it is advisable, in accordance with section 319F–3(a) and (b) of the Act, to provide immunity from liability for covered persons, as that term is defined at section 319F–3(i)(2) of the Act, and to include as such covered persons other qualified persons as I have identified in section VI of the Original Declaration, as amended;

Therefore, pursuant to section 319F–3(b) of the Act, I have determined that 2009 H1N1 influenza and resulting disease constitutes a public health emergency. In order to extend the Original Declaration, as amended, to apply to the 2009 H1N1 influenza and to correct previous, minor, editorial errors, the Original Declaration, as amended, is hereby further amended and republished as follows:

In the title, strike “and H9” and insert “H9, and 2009 H1N1”.

In the first “whereas” clause, first sentence, strike “(H5N1). H7 and H9 vaccines” and insert “H5N1, H7, and H9”.

After the fourth “whereas” clause, insert a new recital as follows:

Whereas, on April 26, 2009, Acting Secretary Charles E. Johnson determined under section 319 of the Public Health Service Act, (42 U.S.C. 247d), that a public emergency exists nationwide involving the 2009 H1N1 influenza virus that affects or has significant potential to affect the national security (now called “2009 H1N1 influenza”);

In the ninth “whereas” clause, insert “;” after “IV”; strike “of the Original Declaration, as amended,”; insert “;” after “VI”; and strike “of the Original Declaration,”.

In the “therefore” clause concluding the recitals, strike the period and insert “, and that the 2009 H1N1 influenza constitutes a public health emergency.”.

In section I, second paragraph, first sentence, strike all after “influenza A” and insert “H5N1, H2, H6, H7, H9, and 2009 H1N1 vaccines and any associated adjuvants.”.

In section I, second paragraph, second sentence, strike all after “influenza A” and insert “H5N1, H2, H6, H7, H9, and 2009 H1N1 vaccines used and administered in accordance with this declaration.”.

Strike the current section II, “Category of Disease,” in its entirety and replace as follows:

II. Category of Disease (as Required by Section 319F–3(b)(2)(A) of the Act)

The category of disease for which I am recommending the administration or use of the Covered Countermeasures is the threat of or actual human influenza that results from the infection of humans following exposure to the virus with (1) highly pathogenic avian influenza A (H5N1, H2, H6, H7, or H9) virus; or (2) 2009 H1N1 influenza.

In section III, strike the period and insert “; except that with respect to 2009 H1N1 influenza vaccine, the effective period commences on June 15, 2009 and extends through March 31, 2013.”

In Section VIII, strike the section in its entirety and replace it with the following:

The Declaration for the Use of the Public Readiness and Emergency Preparedness Act for H5N1 vaccines was published on January 26, 2007 and amended on November 30, 2007 to add H7 and H9 vaccines and on October 17, 2008 to add H2 and H6 vaccines. This Declaration incorporates all amendments prior to the date of its publication in the **Federal Register**. Any future amendment to this Declaration will be published in the **Federal Register**, pursuant to section 319F–2(b)(4) of the Act.

All other provisions of the Original Declaration, as amended, remain in full force.

Republication of HHS Secretary’s Original Declaration, as Amended, for the Use of the Public Readiness and Emergency Preparedness Act for H5N1, H2, H6, H9, and 2009 H1N1 Vaccines

To the extent any term of the original January 27, 2007 Declaration or any amendment thereto is inconsistent with any provision of this republished Declaration, the terms of this republished Declaration are controlling.

HHS Secretary’s Declaration for the Use of the Public Readiness and Emergency Preparedness Act for H5N1, H2, H6, H9, and 2009 H1N1 Vaccines

Whereas highly pathogenic avian influenza A H5N1, H7, and H9 have spread by infected migratory birds and exports of live poultry from Asia through Europe and Africa since 2004, and could spread into North America in 2006 or later, and have caused disease in humans with an associated high case fatality upon infection with this virus;

Whereas, the H2 class of influenza viruses, which caused the human influenza pandemic of 1957 and reappeared recently in U.S. animals including swine, is viewed as a likely candidate to re-evolve into an influenza strain capable of causing a pandemic of human influenza;

Whereas, the H6 class of influenza viruses, which appeared recently in animals including domestic fowl, is viewed as a likely candidate to evolve into an influenza strain capable of causing a pandemic of human influenza;

Whereas, an H5N1, H2, H6, H7 or H9 avian influenza virus may evolve into strain capable of causing a pandemic of human influenza;

Whereas, on April 26, 2009, Acting Secretary Charles E. Johnson determined under section 319 of the Public Health Service Act, (42 U.S.C. 247d), that a public health emergency exists nationwide involving the Swine Influenza A virus that affects or has significant potential to affect the national security (now called “2009 H1N1 influenza”);

Whereas, the possibility of governmental program planners obtaining stockpiles from private sector entities except through voluntary means such as commercial sale, donation, or deployment would undermine national preparedness efforts and should be discouraged as provided for in section 319F–3(b)(2)(E) of the Public Health Service Act (42 U.S.C. 247d–6d(b)) (“the Act”);